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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,819	12/20/2004	Lanna Li	133087.06901(100682-1PUS)	9884
53286 7590 06/12/2008 Pepper Hamilton LLP 400 Berwyn Park 899 Cassatt Road Berwyn, PA 19312-1183			EXAMINER KOSACK, JOSEPH R	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 06/12/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/518,819

**Applicant(s)**

LI, LANNA

**Examiner**

Joseph R. Kosack

**Art Unit**

1626

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 6-11, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 8, 10, 13 and 14 is/are rejected.
- 7) ☒ Claim(s) 6, 9 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-3, 6-11, and 13-14 are pending in the instant application.

#### ***Amendments***

The amendment filed on March 12, has been acknowledged and has been entered into the application file.

#### ***Previous Claim Objections***

Claims 4-8 and 10-12 were previously objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot refer to another multiple dependent claim. Applicant has fixed the dependencies and the objection is withdrawn. Those claims still present in the application will be examined on the merits for this action.

Claims 1-3, 9, and 13-14 were previously objected to for containing elected and non-elected subject matter. The non-elected subject matter has been removed, and the objection is withdrawn.

#### ***Previous Claim Rejections - 35 USC § 103***

Claims 1-3 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanamaru et al. (USPN 5,922,767) in view of Patani et al. (*Chem. Rev.* 1996, 3147-3176).

Applicant has traversed the rejection on the grounds that the references teach T to be in the opposite configuration as to what was claimed and therefore do not suggest the instant claims.

The Examiner must maintain the rejection because the claims do not detail any specific conformation for what the  $N(R^6)C(O)$  group needs to be. As claims are given their broadest reasonable interpretation before the Office, one of skill in the art would determine that both configurations would be claimed by how the claims are written. Therefore, the references adequately suggest the compounds, and the rejection is maintained.

### ***Claim Objections***

Claims 6, 9, and 11 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

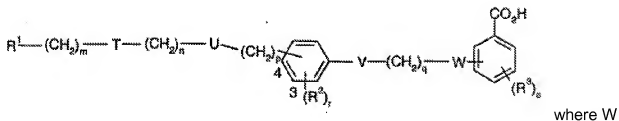
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

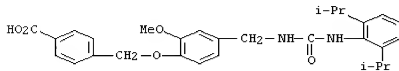
Claims 1-3, 7-8, 10, and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanamaru et al. (USPN 5,922,767) in view of Patani et al. (*Chem. Rev.* 1996, 3147-3176).

The instant claims are drawn to a compound of the formula



is a direct bond, q is 1, V is O, and all other substituents are as defined.

Kanamaru et al. teach a compound of the formula



along with its pharmaceutical

formulation. See compound 34, columns 29-30.

Kanamaru et al. do not teach a linker of  $\text{CH}_2\text{NHC}(\text{O})\text{CH}_2$  in place of the  $\text{CH}_2\text{NHC}(\text{O})\text{NH}$  linker, the protected form of the compound, or the process to deprotect the carboxylic acid.

Patani et al. teach the bioisosteric replacement of  $\text{CH}_2$  for  $\text{NH}$  in a divalent linker. See pages 3155-3156, Especially Tables 19 and 20 and Figures 23 and 24. Protecting groups for carboxylic acids and methods for protecting and deprotecting carboxylic acids are commonly known throughout the chemical arts. The motivation to make the change along with the reasonable expectation of success are provided by Patani et al. which teaches that bioisosterism represents one approach for the medicinal chemist to rationally modify lead compounds into safer and more clinically effective agents. See page 3147.

### ***Conclusion***

Claims 1-3, 7-8, 10, and 13-14 are rejected. Claims 6, 9, and 11 are objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/REI-TSANG SHIAO /  
Primary Examiner, Art Unit 1626

/Joseph R Kosack/  
Examiner, Art Unit 1626